

- (9) Approximate age of device;
- (10) Event problem codes—patient code and device code (refer to FDA MEDWATCH Medical Device Reporting Code Instructions);
- (11) Whether a report was sent to us and the date it was sent (month, day, year);
- (12) Location where event occurred;
- (13) Whether a report was sent to the manufacturer and the date it was sent (month, day, year); and
- (14) Manufacturer name and address, if available.

Subpart E—Manufacturer Reporting Requirements

§ 803.50 If I am a manufacturer, what reporting requirements apply to me?

- (a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:
 - (1) May have caused or contributed to a death or serious injury; or
 - (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.
- (b) What information does FDA consider “reasonably known” to me?
 - (1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you:
 - (i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter;
 - (ii) Any information in your possession; or
 - (iii) Any information that you can obtain by analysis, testing, or other evaluation of the device.
 - (2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.
 - (3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete infor-

mation on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under § 803.56.

§ 803.52 If I am a manufacturer, what information must I submit in my individual adverse event reports?

You must include the following information in your reports, if known or reasonably known to you, as described in § 803.50(b). These types of information correspond generally to the format of FDA Form 3500A:

- (a) Patient information (Form 3500A, Block A). You must submit the following:
 - (1) Patient name or other identifier;
 - (2) Patient age at the time of event, or date of birth;
 - (3) Patient gender; and
 - (4) Patient weight.
- (b) Adverse event or product problem (Form 3500A, Block B). You must submit the following:
 - (1) Identification of adverse event or product problem;
 - (2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it is:
 - (i) Life-threatening injury or illness;
 - (ii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or
 - (iii) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;
 - (3) Date of event;
 - (4) Date of report by the initial reporter;
 - (5) Description of the event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;
 - (6) Description of relevant tests, including dates and laboratory data; and
 - (7) Other relevant patient history including preexisting medical conditions.